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## PRIORITY DOCUMENT

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COMPLIANCE WITH RULE 17.1(a) OR (b)

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

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Signed

Dated 31 August 2004

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Patents Act 1977  
(Rule 16)



**The  
Patent  
Office**

20AUG03 E831466-4 D02136  
P01/7700 0.00-0319461.0

# Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

**19 AUG 2003**

**The Patent Office**

Cardiff Road  
Newport

Gwent NP9 1RH

1.	Your reference	IT/RD/N14459		
2.	Patent application number (The Patent Office will fill this part)	0319461.0		
3.	Full name, address and postcode of the or of each applicant (underline all surnames)	PolyBioMed Limited Sheffield Technology Park 60 Shirland Lane Sheffield, S9 3SP United Kingdom		
	Patents ADP number (if you know it)	07169956001		
	If the applicant is a corporate body, give the country/state of its incorporation			
4.	Title of the invention	Polymers for Controlled Drug Release		
5.	Name of your agent (if you have one)	Williams Powell		
	"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	Morley House 26-30 Holborn Viaduct London EC1A 2BP United Kingdom		
	Patents ADP number (if you know it)	05830310001		
6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number	Country	Priority application number (if you know it)	Date of filing (day / month / year)
7.	If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application.	Number of earlier application	Date of filing (day / month / year)	
8.	Is a statement of inventorship and of right to grant of a patent required in support of this request? (answer 'Yes if:			
	a) any applicant named in part 3 is not an inventor, or			
	b) there is an inventor who is not named as an applicant, or			
	c) any named applicant is a corporate body			

Yes

# Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form.  
Do not count copies of the same document

Continuation sheets of this form

Description

2

Claim(s)

Abstract

Drawing(s)

10. If you are filing one of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination (*Patents Form 10/77*)

Any other documents  
(please specify)

11. I/we request the grant of a patent on the basis of this application.

Signature



Date  
19 August 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

Mr Lee Anderson 020 7936 3300

## Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

## Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

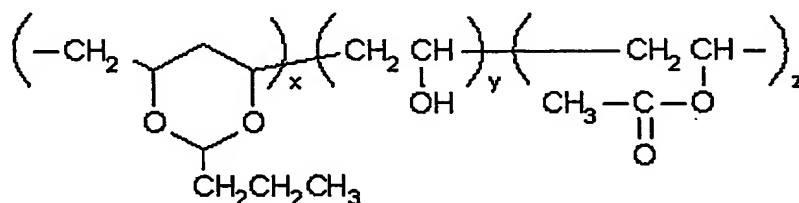
### Polymers for controlled drug release

The present invention relates to a coating composition and to a method for using the composition to coat an implantable medical device. Specifically, it relates to a composition which can be used to coat the surface of a device in combination with a bioactive agent in a manner that permits the surface to release the bioactive agent over time.

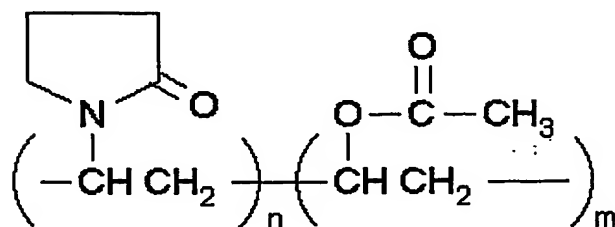
The composition comprises a bioactive agent in combination with a first and optionally a second polymer component. The components are mixed in appropriate proportions to provide a mixture that exhibits an optimal combination of physical characteristics and bioactive release characteristics. For example, a relatively hydrophilic polymer component may be mixed with a relatively hydrophobic polymer component in order to control the characteristics of the resulting composition.

The two preferred polymers are:

1. Poly(vinyl butyral-co-vinyl alcohol-co-vinyl acetate) (PVB)



2. Poly(1-vinylpyrrolidone-co-vinyl acetate) (PnVPA)



PVB is predominantly hydrophobic and comprises the bulk of the formulation, preferably anything from 70% to 100%. Small additions of the hydrophilic PnVPA give the coating its "programmability" in terms of being able to control the release rate of drugs.

The coating is applied through spraying or dipping and dried to remove excess solvent and maintain activity of the drug.

- 10 Depending on the polymer and drug ratios required, adhesion to the surface can be enhanced by means of the method disclosed in WO 03/024500 (in the name of the present applicant), the contents of which are incorporated herein by reference. Where 100% PVB is used, application directly to an unmodified surface may be sufficient (although adhesion may optionally be enhanced by modification techniques). As the amount of PnVPA is increased in the formulation, surface modification is required to maintain adequate adhesion.

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